

K.091131
Pg. 1 of 2

510(k) Summary for the Pelvic Floor Repair System

A. Sponsor

Boston Scientific Corporation
Urology and Gynecology Division
100 Boston Scientific Way
Marlborough, MA 01756

MAY - 8 2009

B. Contact

Michelle Berry
Senior, Regulatory Affairs Specialist
508-683-4941

or

Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Tradename: TBD
Common/usual name: Surgical Mesh
Classification Name: ~~OT~~ - Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename: Pinnacle Pelvic Floor Repair Kit
Common/usual name: Surgical Mesh
Classification Name: ~~OT~~ - Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II
Premarket Notification: Boston Scientific, K071957 and K081048

E. Device Description

The proposed device is a sterile, single use kit, consisting of two synthetic mesh assemblies and a needle holder. Each mesh assembly consists of a polypropylene knitted mesh body with integrated legs that are protected by disposable polymer sleeves. At the distal end of the disposable polymer sleeve is a lead with needle designed for use with the Capiro™ Open Access Suture Capturing Device. The disposable lead was designed to facilitate the passage of the proposed mesh through bodily tissues for placement. The proposed mesh configurations were designed for performing vaginal wall repair to facilitate treatment of anterior, apical and posterior prolapse repairs.

F. Intended Use

The proposed device is intended for tissue reinforcement and stabilization of fascial structures of the pelvic floor for vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

G. Technological Characteristics

The proposed device has the same technological characteristics (i.e. mesh design and mesh material) as the predicates.

H. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" and "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", a direct comparison of key characteristics demonstrates that the proposed mesh is substantially equivalent to the predicate mesh in terms of intended use, technological characteristics, and performance characteristics tested. The proposed device is as safe, as effective, and performs as well as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific
% Ms. Michelle Berry
Senior, Regulatory Affairs Specialist
100 Boston Scientific Way
MARLBOROUGH MA 01760

SEP 28 2012

Re: K091131
Trade/Device Name: Pinnacle Pelvic Repair Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: May 4, 2009
Received: May 5, 2009

Dear Ms. Berry:

This letter corrects our substantially equivalent letter of May 8, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

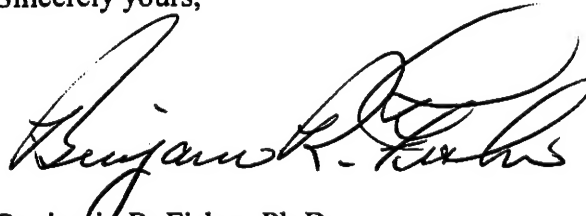
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name "Benjamin" being the most prominent part.

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K091131

Device Name: Undetermined

Indications For Use:

The proposed Pelvic Floor Repair System is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor for vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Prescription Use X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krane for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091131